G1A

Decrease Time

In-Plant

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1A (Activity 1)	Decrease the in-plant time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	The amount of in-plant time to conduct a comprehensive domestic Quality System Inspection
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct comprehensive medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections and report their QSIT in-plant time per subsystem covered during each inspection on an Evaluation Form. Beginning the week of 1/11/99, the in-plant time for conducting domestic QSIT inspections will be tabulated using data extracted from the Evaluation Forms. This time will be compared to the calculated average in-plan time for conducting comprehensive domestic Quality System inspections using the current approach. Overall responsibility for this activity: T. Wells (HFZ-332) and G. Layloff (HFR-SW450)	
Acceptance criteria (if known)	Decrease of in-plant inspectional time.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		This activity will provide a direct and objective measurement of the in-plant inspectional time using the QSIT. This activity will also provide an objective comparison of in-plant inspectional time using the QSIT versus the current approach. The objective comparison will be limited by the need to calculate the average in-plant time for conducting an inspection usin the current approach.
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		This pre-deployment activity objectively measures the satisfaction of the stated goal.

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[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1A	Decrease the in-plant time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	The amount of in-plant time to conduct a comprehensive domestic Quality System Inspection.
Acceptance Criteria	Decrease of in-plant inspectional time.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Each investigator reported their QSIT in-plant time per subsystem covered during each inspection on an Evaluation Form. A tabulation of their reported in-plant times is attached. Average in-plant times for the subsystems were: *Note: 1 day = 6 hours* Management Controls 4.2 hours (0.7 days) Design Controls 5.2 hours (0.9 days) CAPA 10.7 hours (1.8 days) PAPC 8.1 hours (1.3 days) The average total in-plant time was 28.2 hours (4.7 days). The calculated in-plant times for domestic inspections conducted using the non-QSIT approach were: 67.1 hours (11.2 days) (Using PODS baseline data for PACs 82830C and 82830D) 56.9 hours (9.5 days) (Using PODS baseline data for PAC 82830C only) This equates to a 58% reduction (Using PODS baseline data for PACs 82830C and 82830D) or 50.4% reduction (Using PODS baseline data for PAC 82830C only) of in-plant inspection time when using the QSIT for conducting comprehensive inspections of domestic medical device manufacturers.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	The QSIT instructs investigators to conduct a pre-inspection record review. Records are requested during the preannouncement and are provided voluntarily by the firm. As documented in QSIT Validation G1B (Activity 5) 38 of the 42 QSIT Study inspections were pre-announced. Of those 38 firms, only 30 provided records for review. In addition, investigators reported that on 2 occasions there was not enough time to conduct a pre-inspection review of the provided records. This yields pre-inspection record reviews taking	

	place, at best, for 28 (66.7%) of the 42 inspections. When reviews were conducted, the average time expended was 4 hours. Since record review took place at best only 66.7% of the time, the overall average time expended to review records was 2.7 hours. This time should be considered when comparing the QSIT vs non-QSIT in-plant inspection times. If considered, the total time to evaluate the subsystems (in-plant and pre-inspection record review) was 30.9 hours. This then equates to a 53.9% reduction (Using PODS baseline data for PACs 82830C and 82830D) or 45.7% reduction (Using PODS baseline data for PAC 82830C only) of in-plant inspection time.
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)

Item # G1A (Activity 1)

As documented in QSIT Validation Activities G4, and O1A/B, use of the QSIT results in a comprehensive Quality System inspection of a medical device manufacturer.

During the QSIT Study a total of 42 inspections were conducted. As part of the QSIT Study, investigators reported their QSIT in-plant time per subsystem for each inspection on an Evaluation Form. The data are tabulated in Attachment 1.

The average in-plant time for conducting a QSIT inspection was determined to be 28.2 hours. Defining a "day" as 6 hours, this equates to 4.7 inspection days in the plant.

Since the G1A goal is expressed in terms of a **decrease** in the in-plant time for conducting comprehensive domestic Quality System inspections, the in-plant QSIT inspection time must be compared to the in-plant time spent when conducting a comprehensive inspection using the current approach.

The PODS time reporting system for investigators tracks total inspection time, it does not track in-plant inspection time. Therefore, for the purpose of making a comparison to determine if indeed there was a decrease of in-plant time, the following formula was used to calculate in in-plant time spent when conducting inspections using the current approach.

Total inspection time is made up of three elements: Preparation Time, In-plant Time and Report Write-up Time.

$$P + I + W = T$$

PODS does not track Preparation Time. However, based on the inspectional experience of QSIT Team investigators, the average Preparation Time was estimated to be 8 hours.

$$8 + I + W = T$$

PODS does not track Report Write-up time. However, per the Investigator EPMS element #2 (Fully Successful), that was in effect in FY98, "Write up time does not exceed 35 percent of on-site inspection time, without justification." For this formula the maximum allowable, without justification, write up time of 35 percent will be used.

$$8 + I + .35\ I = T$$

As previously stated, total inspection time is tracked in PODS. Time is tracked per type of inspection performed. For several years, and in accordance with the Compliance Program 7382.830 directive, investigators performing comprehensive domestic medical device inspections reported their time only using PAC 82830C.

With the 6/1/97 implementation of the design control requirements and the new Quality System regulation, investigators were directed per a 5/2/97 email from ORO (D. Dion) to report domestic inspectional time covering design controls under the separate PAC 82830D. This directive was reinforced by HFZ-305 (W. Morganstern/M. Hoban) in the 7/24/97 Monthly Conference Call for Medical Device Investigators. Additionally, the FY 98 workplan directed,

"Design control requirements should be evaluated and reported on the Design Control Inspectional Strategy Report. Report all time used for evaluating design controls and completing the report against PAC 82830D."

The Compliance Program 7382.830 remains as a draft document, and has not been updated to reflect the new 82830D PAC. However, effective 6/1/97, the total time to conduct a comprehensive domestic medical device inspection became a combination of the time reported under PAC 82830C and the time reported under PAC 82830D.

Per an 11/25/98 POVAC data run, covering the period 10/1/97 – 9/30/98, the accomplished time per operation was reported as: PAC 82830C 84.8 hours; PAC 82830D 13.8 hours. This totals 98.6 hours and reflects the time spent to conduct a comprehensive domestic medical device inspection including design controls.

If the assumptions made on preparation and write-up are accurate, then the following calculation can be made:

$$8 + I + .35I = 98.6$$
$$1.35I = 90.6$$

$$I = 67.1$$

Defining a "day" as 6 hours, this equates to 11.2 inspection days in the plant.

If a calculation of in-plant time were made using only the PAC 82830C time of 84.8 hours, the in-plant time would be 56.9 hours (9.5 days).

Depending on which PODS data are used to establish a baseline, either 67.1 hours (11.2 days) or 56.9 hours (9.5 days) are best estimates for in-plant time using the non-QSIT approach.

As reported above, the in-plant time using the QSIT approach was 28.2 hours (4.7 days).

> *Note: The QSIT instructs investigators to conduct a pre-inspection record review. Records are requested during the preannouncement and are provided voluntarily by the firm. As documented in QSIT Validation G1B (Activity 5) 38 of the 42 QSIT Study inspections were pre-announced. Of those 38 firms, only 30 provided records for review. In addition, investigators reported that on 2 occasions there was not enough time to conduct a pre-inspection review of the provided records. This yields pre-inspection record reviews taking place, at best, for 28 (66.7%) of the 42 inspections. When reviews were conducted, the average time expended was 4 hours. Since record review took place at best only 66.7% of the time, the overall average time expended to review records was 2.7 hours. This time should be considered when comparing the QSIT vs non-QSIT in-plant inspection times.*

Attachment 1 - Item # G1A (Activity 1)

IN-PLANT INSPECTION TIME
(Hours)

Inspection Code	Management Controls	Design Controls	CAPA	PAPC	Total
1A1	6	6	6	6	24
1A2	3	6	9	3	21
1A3	3	6	6	3	18
1A4	3	0	6	6	15
1B1	10	0	30	20	60
1B2	6	0	8	10	24
1B3	4	0	10	10	24
1C1	9	7	15	9	40
1C2	4	2	5	5	16
1C3	9	4	15	17	45
1C4	9	12	15	13	49
1D1	3	4	20	5	32
1D2	4	8	20	11	43
1D3	2	2	3	9	16
1D4	4	10	18	7	39
2A1	4	0	10	8	22
2B1	3	12	19	7	41
2B2	5	18	35	4	62
2B3	5	10	11	8	34
2C1	4	0	8	12	24
2C2	4	12	12	12	40
2C3	2	7	10	10	29
2C4	3	8	10	8	29
2D1	4	4	6	4	18
2D2	4	6	8	8	26
2D3	2	4	4	4	14
2D4	4	0	7	7	18
3A1	4	12	12	6	34
3A2	2.5	1.5	5	6	15
3A3	4	10	12	16	42
3A4	3	6	8	5	22
3B1	3	1	5	13	22
3B2	5	6	16	10	37
3B3	4	6	17	13	40
3B4	2.5	4	11	5	22.5
3C1	1	6	6	8	21
3C2	3	1	6	8	18
3C3	2	1	6	4	13
3C4	2	4	5	5	16
3D1	8	5	8	8	29
3D2	2	.5	3	4	9.5
3D3	6	5	5	4	20
Total Time	175	217	451	341	1184
Avg. Time	4.2	5.2	10.7	8.1	28.2
Avg. Days (1 day = 6 hours)	.7	.9	1.8	1.3	4.7